

Claim Amendments

Claim 1 (currently amended): A system for assisting flow of blood by a patient's heart comprising:

a transseptal cannula adapted to be inserted percutaneously in the femoral vein and extend through the atrial septum from the right atrium to the left atrium;

an extracorporeal blood pump mechanism having a blood pump for pumping blood received from the left atrium through the transseptal cannula that has been oxygenated, the blood pump inlet connected to the transseptal cannula, the blood pump mechanism includes a transseptal clamp mechanism which clamps the blood pump to the transseptal cannula to avoid undesired disconnection of the blood pump and the transseptal cannula and undesired leaks in a connection joint formed between the blood pump and the transseptal cannula; and

a perfusion cannula adapted to be inserted percutaneously in the femoral artery for returning oxygenated blood to the arterial system of the patient, the perfusion cannula connected to the blood pump outlet, and tubing which connects the blood pump to the transseptal cannula and the perfusion cannula, the blood pump disposed connected by the

tubing which is within three feet in length of where the transseptal cannula and the perfusion cannula are positioned to enter the patient.

Claims 2 and 3 (canceled)

Claim 4 (currently amended): A system as described in Claim 1 wherein the blood pump mechanism includes tubing which connects the blood pump to the transseptal cannula and the perfusion cannula and the clamp mechanism clamps the tubing between the blood pump and the transseptal cannula.

Claim 5 (original): A system as described in Claim 4 wherein the tubing has a continuous smooth inner surface.

Claim 6 (original): A system as described in Claim 5 wherein the blood pump pumps a continuous flow of blood.

Claim 7 (original): A system as described in Claim 6 wherein the blood pump has a rotor and a stator.

Claim 8 (original): A system as described in Claim 7 wherein the blood pump mechanism includes a controller connected to the blood pump through which the operation of the blood pump speed is adjusted.

Claim 9 (original): A system as described in Claim 8 wherein the blood pump includes an impeller which moves against the blood, and the controller adjusts the operation of the blood pump by changing impeller speed.

Claim 10 (original): A system as described in Claim 9 wherein the controller estimates blood flow rate through the pump only by measuring impeller speed and stator current.

Claim 11 (original): A system as described in Claim 9 wherein the blood pump mechanism includes an electromagnetic or ultrasonic flow probe in communication with the blood pump and the controller measures flow of blood through the pump with the electromagnetic or ultrasonic flow probe.

Claim 12 (original): A system as described in Claim 10 wherein the pump has a hydrodynamic bearing between the rotor and the stator.

Claim 13 (original): A system as described in Claim 12 wherein the blood pump mechanism includes a fluid reservoir and a fluid pump connected to the fluid reservoir and the blood pump to pump fluid to the blood pump and the hydrodynamic bearing.

Claim 14 (original): A system as described in Claim 13 wherein the fluid reservoir and the fluid pump connected to the blood pump form an infusion system, and the infusion system is used to monitor for bearing system faults and anticoagulation faults.

Claim 15 (original): A system as described in Claim 14 wherein the fluid reservoir includes predetermined concentrations of drugs.

Claim 16 (original): A system as described in Claim 15 wherein the pump controller provides current to the blood pump and the controller includes a battery that provides energy to run the controller and the blood pump, the battery is used for powering the blood pump and controller when the patient is being moved between remote locations.

Claim 17 (original): A system as described in Claim 16 wherein the blood pump is made of biocompatible materials which have no effect on blood or the patient.

Claim 18 (original): A system as described in Claim 9 wherein the blood pump is a centrifugal pump or an axial pump.

Claim 19 (original): A system as described in Claim 18 wherein the blood pump mechanism includes a controller connected to the blood pump through which the operation of the blood pump speed is adjusted.

Claim 20 (original): A system as described in Claim 19 wherein the controller monitors for single point faults, detects and manages them, and alerts users of fault status.

Claim 21 (original): A system as described in Claim 5 wherein the blood pump is a pulsatile, electrical or pneumatic pump having an inflow valve and a perfusion valve.

Claim 22 (previously presented): A system as described in Claim 20 wherein the pump is a pulsatile pump having a stroke time, and the controller adjusts the operation of the blood pump by adjusting stroke time.

Claim 23 (original): A system as described in Claim 22 wherein the pump controller provides current to the blood pump and the controller includes a battery that

provides energy to run the controller and the blood pump, the battery is used for powering the blood pump and the controller when the patient is being moved between remote locations.

Claim 24 (original): A system as described in Claim 3 including a holding mechanism which holds the blood pump and attaches to the patient.

Claim 25 (original): A system as described in Claim 24 wherein the holding mechanism includes a pump holding portion which holds the pump and a patient portion which is adapted to fit to the leg of the patient and to secure to the pump holding portion.

Claim 26 (original): A system as described in Claim 25 wherein the pump holding portion is made of plastic having an imprint of the shape of the blood pump in which the blood pump fits to be held by the pump holding portion, and the patient holding portion includes a band with loops and with straps having hooks adapted to wrap about the leg and the pump holding portion to hold the pump holding portion to the leg.

Claim 27 (original): A system as described in Claim 26 wherein the holding mechanism is adapted to attach to either leg of the patient and allow inflow or out flow to be connected to the contralateral side of the patient.

Claim 28 (original): A system as described in Claim 27 wherein the holding mechanism is adapted to hold the blood pump in a normal position or at an angle of 20 degrees from the normal position.

Claim 29 (currently amended): A method for assisting blood flow by a patient's heart comprising the steps of:

inserting percutaneously in the femoral vein of the patient and extending through the atrial septum from the right atrium to the left atrium a transseptal cannula;

inserting percutaneously in the femoral artery a perfusion cannula for returning oxygenated blood to the arterial system of the patient;

~~positioning a blood pump within three feet of where the transseptal cannula and the perfusion cannula are inserted into the patient;~~

clamping a transseptal clamp mechanism to tubing within three feet of length connected to the transseptal cannula and [[the]] a blood pump to avoid undesired disconnection of the blood pump and the transseptal cannula and undesired leaks at a connection joint formed between the blood pump and the transseptal cannula; and

pumping blood with the blood pump through the tubing connected to the transseptal cannula and tubing within three feet of length connected to the blood pump and the perfusion cannula at specified flow rates over a range of physiological pressures.

Claims 30 and 31 (canceled)

Claim 32 (previously presented): A method as described in Claim 29 wherein the pumping step includes the step of pumping a continuous flow of blood with the blood pump.

Claim 33 (original): A method as described in Claim 32 wherein the pumping step includes the step of adjusting the flow of blood pumped with a controller connected to the blood pump.

Claim 34 (original): A method as described in Claim 33 wherein the adjusting step includes the step of adjusting impeller speed of an impeller of the blood pump to attain a desired flow of blood in the patient due to the operation of the blood pump.

Claim 35 (original): A method as described in Claim 34 including after the pumping step, there is the step of powering the controller and the blood pump with a battery as the patient is moved from a first location to a second location remote from the first location.

Claim 36 (original): A method as described in Claim 35 including before the pumping step, there are the steps of attaching a holding mechanism for the blood pump to the patient and placing the blood pump in the holding mechanism to hold the blood pump in place relative to the patient.

Claim 37 (original): A method as described in Claim 36 wherein the attaching step includes the step of attaching the holding mechanism to the leg of the patient.

Claim 38 (original): A method as described in Claim 37 wherein the placing step includes the step of wrapping straps of a band positioned about the leg of the patient, about the blood pump, and fixing hooks of the straps to loops of the band to secure the blood pump to the leg of the patient.

Claim 39 (original): A method as described in Claim 31 wherein the pumping step includes the step of pumping pulses of blood through the patient with a pulsatile pump.

Claim 40 (original): A method as described in Claim 39 wherein the pumping step includes the step of adjusting stroke timing of the pulsatile pump to obtain the desired pulse of blood flow through the patient.

Claim 41 (previously presented): A system as described in Claim 1 including means for delivering additional fluid into oxygenated blood by injecting a specific fluid into the blood pump mechanism.

Claim 42 (previously presented): A system as described in Claim 41 wherein the delivering means includes an infusion system having an IV bag and the additional fluid is injected into the IV bag, and the fluid delivery depends upon the amount of fluid injected and the constant flow rate of the infusion system.

Claim 43 (canceled)

Claim 44 (original): A system as described in Claim 1 including a control system having a primary monitor and a backup monitor with a watchdog for monitoring the primary and backup monitors and independent redundant monitoring primary monitor and redundant backup monitor, the primary and backup, and redundant primary and redundant

backup monitors each able to detect and manage single point faults of the system without requiring a dedicated 24 hours/day human surveillance.

Claim 45 (original): system as described in Claim 1 wherein the pump mechanism has a pump inlet and provides circulatory support of blood flow over an entire physiologic pressure range without cavitation caused by excessive vacuum pressure at the pump inlet.

Claims 46 and 47 (canceled)

Claim 48 (previously presented): A method as described in Claim 29 including the step of implementing the inserting steps and the pumping step that can be implemented in a short time so as be practical for emergent use without open-chest surgery.

Claim 49 (original): A system as described in Claim 1 wherein the pump mechanism includes a motor and a controller having a motor control circuit that monitors motor drive output and initiates a logic signal when motor speed and direction as fed back from the motor does not agree with motor commands being output by the motor control circuit.

Claim 50 (original): A system as described in Claim 1 including a controller that can detect abnormal flow faults in a < 50ml/hour fluid flow pump mechanism based on the cyclic pressure profile of the pump mechanism.

Claim 51 (previously presented): A system as described in Claim 1 wherein the transseptal cannula and the perfusion cannula are each interchangeable to quickly access or redistribute blood to a certain destination in a patient's body by changing appropriate sizes of the respective cannula.

Claim 52 (previously presented): A system for assisting flow of blood by a patient's heart comprising:

a transseptal cannula adapted to be inserted percutaneously in a vein and extend through the atrial septum from the right atrium to the left atrium;

an extracorporeal blood pump mechanism having a blood pump for pumping blood received from the left atrium through the transseptal cannula that has been oxygenated, the blood pump inlet connected to the transseptal cannula;

a controller connected to the blood pump through which the operation of the blood pump speed is adjusted; and

a perfusion cannula adapted to be inserted percutaneously in an artery for returning oxygenated blood to the arterial system of the patient, the perfusion cannula connected to the blood pump outlet, the extracorporeal blood pump is disposed within three feet of where the transseptal cannula and the output cannula are positioned to enter the patient.